#### REMARKS

Claims 40-55 are pending in the application.

## Allowable subject matter

Applicants thank the examiner for acknowledging that claims 40-45 are allowed.

## Claim objections

The misspelling of heterodimerization in claim 52 has been corrected, obviating the objection to this informality.

## Claim rejections under 35 USC § 112

Claim 53 is rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The examiner asserts that it is not clear if the term "characterized" in the claim represents open or closed transitional language, and has interpreted the term as open language, akin to "comprising."

Claim 53 has been amended to recite "consisting essentially of" in place of "characterized," obviating the rejection. Withdrawal of this rejection is respectfully requested.

### Claim rejection under 35 USC § 102(b)

Claims 46-51 and 53-55 are rejected under 35 USC 102(b) as being anticipated by US Patent Number 5,656,725 ("the '725 patent").

The examiner has denied Applicants' priority claim to the '725 patent, asserting that SEQ ID NO:36 does not appear in the parent application and that one of skill would not have been led from SEQ ID NO:2 of the parent application to the instant SEQ ID NO:36. Therefore, the examiner asserts that the '725 patent is prior art against the instant application and further asserts that the '725 patent teaches a method of screening for

modulators of the interaction of a sequence comprising SEQ ID NO:36 (encompassed in SEQ ID NO:2) and Bcl- $X_L$ .

Applicants have amended claims 46 and 53 to recite "consisting essentially of SEQ ID NO:36." In view of this amendment, the disclosure of SEQ ID NO:2 (comprising SEQ ID NO:36) in the '725 patent does not anticipate the instant claims and withdrawal of this rejection is respectfully requested.

## Double patenting rejections

Claims 46-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of US Patent No. 6,221,615 ("the '615 patent"). The examiner asserts that patented claim 1 closely parallels and embraces the instantly claimed invention as the patented claim recites a method of identifying modulators of heterodimerization of any of SEQ ID NOS: 1-10, wherein SEQ ID NOS: 1-10 comprise an amino acid sequence found in instantly claimed SEQ ID NO:36, and a polypeptide of Bcl-X<sub>L</sub>.

In view of the amendments to claims 46 and 53, Applicants respectfully submit that the instantly claimed methods are not obvious variations of patented claim 1. The instant invention is drawn to methods of identifying modulators of heterodimerization of a polypeptide consisting essentially of SEQ ID NO:36 and Bcl-X<sub>L</sub>. It would not have been obvious to one of ordinary skill in the art to use a truncated version of SEQ ID NO:2, as encompassed in a polypeptide consisting essentially of SEQ ID NO:36, in the method described in patented claim 1 of the 615 patent.

In other words, the claims of the instant patent are directed to a method of identifying a GD domain-mediated heterodimerization modulator which modulates heterodimerization of polypeptides consisting essentially of SEQ ID NO: 36 and Bcl-x<sub>L</sub>. SEQ ID NO: 36 comprises a polypeptide of 20 amino acids, viz., TMGQVGRQLAIIGDDINRRY, which is different in composition from that disclosed in SEQ ID NOS: 1-10. Moreover, the modulator in the instant case modulates the

heterodimerization activity between SEQ ID NO: 36 and Bcl-x<sub>L</sub>. No such interaction is claimed in the '615 patent.

Patented claim 1 of the '615 patent does not disclose that the first or second polypeptide can be labeled. However, the examiner asserts that the specification of the '615 patent teaches that the Bcl-X<sub>L</sub> polypeptide can be labeled as instantly claimed, and also teaches the method of identifying such inhibitors that comprise augmentation or inhibition of heterodimerization. Applicants respectfully submit that the examiner is improperly using the disclosure of the '615 patent as prior art, in contrast to the guidelines of Section 804(II.B.1) of the MPEP ("When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art.").

In view of the foregoing, Applicants respectfully request withdrawal of the obviousness-type double patenting rejection of claims 46-55 over claim 1 of the '615 patent.

Claims 46-55 are also rejected under obviousness-type double patenting as being unpatentable over claim 1 of US Patent No. 5,656,725 ("the '725 patent"). The examiner asserts that the instant claims are not patentably distinct from patented claim 1 because patented claim 1 claims compounds that are used in the presently claimed methods. The examiner further asserts that because the specification of the '725 patent discloses processes of screening for inhibitors of heterodimerization between the compounds of patented claim 1, and because methods of using compounds are considered obvious over the compounds themselves, the instantly claimed method of screening for inhibitors of heterodimerization is considered obvious over the patented claim.

Applicants respectfully submit that the obviousness-type double patenting rejection is improper since the claims in the instant application and claim 1 of the '725 patent are patentably distinct. Patented claim 1 of the '725 patent claims an isolated and purified peptide having an amino acid sequence selected from the group consisting of amino acid sequences as set forth as SEQ ID NOS:1-10. In view of the amendments to claims 46 and 53 to recite polypeptides consisting essentially of SEQ ID NO:36,

Applicants submit that the presently claimed methods do not utilize compounds of patented claim 1.

As explained above, the claims of the instant patent are directed to a method of identifying a GD domain-mediated heterodimerization modulator which modulates heterodimerization of polypeptides consisting essentially of SEQ ID NO: 36 and Bcl-x<sub>L</sub>. SEQ ID NO: 36 comprises a polypeptide of 20 amino acids, viz., TMGQVGRQLAIIGDDINRRY, which is different in composition from that disclosed in SEQ ID NOS: 1-10. Moreover, the modulator in the instant case modulates the heterodimerization activity between SEQ ID NO: 36 and Bcl-x<sub>L</sub>. No such interaction is claimed in the '725 patent.

Applicants also respectfully submit that the examiner is improperly using the disclosure of the '725 patent of screening methods for inhibitors of heterodimerization as prior art, in contrast to the guidelines of Section 804(II.B.1) of the MPEP. Patented claim 1 of the '725 patent claims compounds of SEQ ID NOS: 1-10, not methods of screening for inhibitors of heterodimerization of compounds of SEQ ID NOS: 1-10, and as such cannot be considered to render obvious the instantly claimed method of screening for inhibitors of heterodimerization. Furthermore, the examiner has not presented any reasons to support his assertion that methods of using compounds are obvious over the compounds themselves.

In view of the foregoing, Applicants respectfully request withdrawal of the obviousness-type double patenting rejection of claims 46-55 over claim 1 of the '725 patent.

# **CONCLUSION**

Although no fee is believed to be due at this time, the Commissioner is authorized to deduct any fee that may be necessary to maintain the pendency of this application from PTO Deposit Account No. 08-0219. Should there be any questions, the undersigned can be contacted at the below-listed telephone number.

Respectfully submitted,

Henry M. Wixor

Registration No. 32,073

Date: 15 AUGUST 2005

Wilmer Cutler Pickering Hale and Dorr LLP

1455 Pennsylvania Avenue, NW

Washington, DC 20004

202-942-8400 (telephone)

202-942-8484 (facsimile)